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BY ECF/EMAIL

Honorable Mary Kay Vyskocil
United States District Judge
Southern District of New York
500 Pearl Street
New York, New York 10007

RE: *United States v. Seth Fishman and Lisa Giannelli*, S6 20 Cr. 160 (MKV)

Dear Judge Vyskocil:

The Government writes in reply to the defendants' opposition to the Government's motions *in limine* (the "Opp'n" (ECF No. 599)). For the Court's reference, the Government responds to each of the responses the defense provides in the order corresponding with the Government's initial motion. For all the reasons provided in the Government's papers, the defendants' objections are either meritless or moot.

First, the defense concedes—as it must—that statements of the defendants and statements attributable to the defendants are admissible subject to an analysis of their probity and prejudicial effect, pursuant to Rules 401 and 403. Opp'n at 4. The Government does not dispute that any non-hearsay statements, or statements falling within a hearsay exception, offered by the Government may be subject to objections on other grounds.

Second, the defense argues that the defendants should not be precluded from offering their own statements if not offered for the truth of the matter. *See* Opp'n at 4-5. The defense provides no specificity regarding a particular statement they anticipate calling at trial. They instead point to a call between Seth Fishman and a foreign purchaser quoted in the Government's motion, and argue that the Court should admit "[e]vidence designed to put this statement into context" and "evidence regarding the intent of the defendant's 'programs'" as relevant to Fishman's state of mind. *Id.* at 5-6. The defense is simply incorrect to presume that they have *carte blanche* to introduce any hearsay statements on the basis that they would purportedly "contextualize" the Government's evidence. Absent a further proffer by the defendants of which statements they seek to admit, and the basis for their admission, the defendants should be precluded from offering such evidence on this basis.

Third, the parties are in agreement that Seth Fishman may open the door to his own proffer-protected statements, provided subject to a limited grant of immunity, based on evidence, argument, or questioning offered by Fishman or his counsel. Opp'n at 8-9. The defendants argue

that the Government's motion is, at this point, premature, but may be ripe for the Court's review soon after trial has commenced. The defendants are correct as a technical matter, however, that the arguments already stated or implied in their pretrial briefing—including claims that Fishman's "programs" were designed to do anything other than covertly improve performance through the use of Fishman's drugs, *see* Opp'n at 9—would be precisely the kinds of arguments that would open the door to Fishman's proffered statements in direct contradiction of that false notion.

Fourth, the defense has stated that they do not intend to offer evidence or argument speculating as to why other individuals or entities were not the subject of criminal prosecution. Opp'n at 3. As such, this motion is moot.

Fifth, the defense seeks to cross examine any government witnesses regarding matters that may "demonstrate bias, failure of memory, or other behavior demonstrating a lack of credibility," Opp'n at 13, consistent with the areas of cross-examination anticipated by the Government. As such, the parties seem to agree that these would be permissible bases for questions on cross-examination absent objections under Rule 403, while questions regarding the overarching scope of the investigation and other matters beyond the scope of direct testimony are not proper grounds of inquiry. Consequently, this motion is also moot.

Sixth, while the defense has stated that they do not wish to invoke an advice of counsel defense—thereby avoiding the waiver of privilege and discovery obligations that accompany such a defense—they maintain that they each "retain[]" the right to elicit evidence, including evidence of consultation with counsel, to the extent that it is relevant to demonstrate a lack of intent to commit the crimes charged." Opp'n at 3. The defense's proposed exception swallows the well-established rule that advice of counsel may not act as a sword and a shield – invocation of advice, while *implying* that the content of that advice was exculpatory, constitutes a waiver of privilege and obligates the defendants to produce materials relating to the purported advice and the basis on which it was provided.

Courts in this District have rightly viewed this so-called "presence of counsel" defense with skepticism, mindful that it risks injecting irrelevant or prejudicial information into criminal trials. As to the potential prejudice, from a legal standpoint, the presence of counsel defense is in no way materially different from the advice of counsel defense, which "is not an affirmative defense that defeats liability even if the jury accepts the government's allegations as true," but is, instead, evidence that "if believed, can raise a reasonable doubt in the minds of the jurors about whether the government has proved the required element of the offense that the defendant had an unlawful intent." *United States v. Scully*, 877 F.3d 464, 476 (2d Cir. 2017). Because an established body of law, developed under the rubric of the advice of counsel defense, governs when and how criminal defendants are entitled to rely on the involvement of lawyers to negate *mens rea*,¹ courts

¹ A true advice of counsel defense requires a defendant to show "that he (1) honestly and in good faith sought the advice of counsel; (2) fully and honestly la[id] all the facts before his counsel; and (3) in good faith and honestly follow[ed] counsel's advice, believing it to be correct and intending that his acts be lawful." *United States v. Colasuonno*, 697 F.3d 164, 181 (2d Cir. 2012) (internal quotations omitted).

have been reluctant to endorse a “presence of counsel” defense that would allow a defendant to functionally mount an advice of counsel defense without meeting the required elements.

Thus, for example, in *SEC v. Tourre*, 950 F. Supp. 2d 666, 683-84 (S.D.N.Y. 2013), the Court precluded the defendant from highlighting the fact that a lawyer participated in certain communications and transactions once it was clear that the defendant could not show a valid advice of counsel defense. In precluding the defendant from presenting anything short of a proper advice of counsel, the Court explained:

A lay jury could easily believe that the fact that a lawyer is present at a meeting means that he or she must have implicitly or explicitly “blessed” the legality of all aspects of a transaction. Likewise, the fact that lawyers saw and commented on disclosure language could be understood as “blessing” the sufficiency of that disclosure. This misunderstanding would give the defendant all of the essential benefits of an advice of counsel defense without having to bear the burden of proving any of the elements of the defense.

Id. See also *United States v. Petit*, No. 19 Cr. 850 (JSR) (ECF No. 185 (Trial Tr.) at 2092-2093) (noting at trial that defense counsel “has been quite good in avoiding” raising presence of counsel and accountant issues, but that if they raise it in summation “I will probably interrupt right then and there and say ‘There is no defense of counsel here, there is no auditor advice defense.’”); *SEC v. Stoker*, No. 11 Civ. 7388 (JSR) (S.D.N.Y. 2012) (ECF No. 100 (Trial Tr.) at 895-96) (“[A]bsent evidence that counsel knew either the information that Mr. Stoker allegedly kept secret, from outsiders, or knew the information that the SEC claims were distorted misrepresentations, the role of counsel in any of this [was] totally irrelevant.”); *SEC v. Lek Securities Corp.*, 17 Civ. 1789 (DLC), 2019 WL 5703944, at *4 (S.D.N.Y. Nov. 5, 2019) (“References to counsel’s communications are not relevant in the absence of an advice-of-counsel defense and should be excluded as well pursuant to Rule 403.”).

Lay juror misperception is precisely what the defendants invite here. Beyond enabling the defendants to benefit from an incomplete advice of counsel defense, the presence of counsel defense risks injecting irrelevant or confusing evidence into this trial, because the involvement of counsel in a scheme is not probative of a defendant’s state of mind unless it is established that the counsel was informed of all relevant facts regarding the scheme. Proof that the defendants consulted with counsel—without any elucidation of the facts proffered to counsel, or the advice received—has no relevance whatsoever to each defendant’s state of mind. That the defendants sought the advice of attorneys at some point in the course of their conspiracy (or that they did so following their arrest²) is irrelevant to their state of mind without proof of the nature of that advice

² In Seth Fishman’s application for deferred prosecution and in his pre-trial filings he has pointed to post-arrest consultations with counsel apparently well-versed in the Food Drug and Cosmetic Act (“FDCA”). It is hardly uncommon for defendants, after their arrest, to seek out counsel regarding their defense. Such post-arrest meetings have no bearing at all on Fishman’s state of mind prior to his arrest, and no relevance to his state of mind regarding his continued violations of the law absent evidence of the information given, the advice rendered, and actions in conformity therewith.

and proof suggesting that they followed the advice received. On the other hand, evidence of such consultation is highly prejudicial insofar as the jury would infer that whatever advice was rendered by counsel (which the defendants do *not* seek to admit) was followed. Yet there is no way to meaningfully test those assumptions absent a review of attorney-client communications.³

As such, admitting at trial evidence that the defendants met with attorneys is irrelevant, is highly prejudicial, misleading and ought to be barred. There is no admissible foundation to show that such counsel were apprised of all the material facts of the scheme, such that their presence would be probative of the defendants' state of mind. Nor is there adequate evidence of the nature and scope of counsel's advice, as would be the case if the defendants were asserting a true advice-of-counsel claim. Absent a sufficient foundation, the mere presence of lawyers would serve no purpose other than to mislead the jury into believing that a lawyer had "blessed" the defendants' conduct. The invocation of lawyers in that way would be highly prejudicial to the Government and should be excluded under both Rules 401 and 403.

Seventh, the defense has stated that they do not intend to offer a defense of public authority or entrapment by estoppel. Opp'n at 3. As such, this motion is likewise moot.

Eighth, the defense does not object to the Government's motion to preclude evidence or argument regarding personal characteristics or history unconnected to guilt, or discussions of punishment. Given that the Government's motion on this score is uncontested, the Court should grant this motion in full.

Ninth, the defendants' objections to the introduction of the Delaware State Division of Professional Regulation's investigation into Fishman and Giannelli are meritless. the existence of the investigation and the defendants' misrepresentations to investigators is direct proof of Fishman and Giannelli's intent to mislead or defraud a state agency charged with (among other things) consumer protection and drug regulation, and the contents of the complaint lodged against them reflect the exact nature of the victim and the misleading statements and fraud. The defendants are both incorrect and focused on an irrelevancy.

The defendants first incorrectly suggest that "there is no mention in the documents and testimony" that the defendants were investigated for violations of the FDCA and thus it "does not demonstrate the defendant's knowledge of the relevant portions of the FDCA." Opp'n at 7. To the contrary, the complaint filed against them specifically charges Giannelli with "dispensing medications that are not approved in the US *which is also a FDA* and potentially a DEA violation." Gov. MIL (ECF No. 572) Exhibit B (emphasis added).

³ Importantly, in the event the defendants are permitted to introduce such evidence or argument, they should also be required to produce any evidence upon which they would rely in support thereof, regardless of whether a claim of privilege may attach to that evidence. *See United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) (recognizing that a defense based on interactions and communications with lawyers may waive the attorney-client privilege with respect to those dealings).

Moreover, the statutory foundation of particular violations under investigation, though probative given that they actually included reference to federal drug laws, is ultimately not a prerequisite to admissibility. In the course of their conspiracy – *i.e.*, in order to avoid detection and to continue their misbranding activities – Fishman and Giannelli misled a state drug regulator. That Fishman and Giannelli lied to this investigator in the course of this particular investigation, regardless of any citation to the FDCA, is sufficient to demonstrate the relevant felonious intent.

Finally as to this ninth point, other specific allegations to which the defendants (falsely) responded when evading liability in Delaware speak directly to the defendants’ fraudulent intent in the years following the Delaware investigation. For example, principles of veterinary practice and drug distribution—such as establishing a valid veterinarian-client-patient relationship—are imbued throughout both state law and the FDCA. The defense’s request that the complaint be “redacted to eliminate reference . . . to the allegation that the defendant [Fishman] failed to establish VCPR with this animal” once again misses the mark. The import of this evidence is that Fishman and Giannelli learned in no uncertain terms the prerequisites and limitations to dispensing unapproved prescription drugs and continued this practice for approximately a decade thereafter. This proof has a direct bearing on their intent to defraud or mislead state and federal drug regulators.

Tenth, the defense objects to the introduction of statements made by Seth Fishman to the Federal Bureau of Investigation and the U.S. Attorney’s Office for the Eastern District of New York (“EDNY”) with respect to the prosecution of David Brooks, absent a showing that the defendant has “opened the door” to such statements.⁴ The defendant’s objection lacks support. Fishman initially proffered with the EDNY on or about October 13, 2010, pursuant to a proffer agreement offering limited protections, and with the participation of Fishman’s counsel. In subsequent meetings with the prosecutors in the EDNY, Fishman voluntarily provided information without the benefit of a proffer agreement, and without the participation of his attorney. The proffer agreement entered into by the parties was only applicable as to the initial meeting. There is no signed proffer agreement governing subsequent meetings between Fishman and the Brooks prosecution team, and the notes taken of those meetings (which specify that information was given voluntarily and without the presence of counsel) indicate as much. Defense counsel cites no support for their contention that the initial proffer agreement extended beyond the first conversation to all interactions between Fishman and that prosecution team, and that position is expressly foreclosed by the terms of the proffer agreement itself. Consequently, Fishman’s objection to the introduction of those statements is baseless; given that his statements to the EDNY are statements by the defendant and not subject to any protections, they are admissible in the Government’s case in chief irrespective of whether Fishman “opens the door” to these statements, as argued in the Government’s motion *in limine*.

⁴ The defense requests “written notice and an opportunity to brief the issue and to be heard” regarding the Government’s intent to admit these statements. Opp’n at 3 n.1. The request is moot, as the Government has already specifically raised and briefed this issue in its December 1, 2021 motions *in limine*. The defendant’s papers constitute its “opportunity to brief the issue” and no further briefing is warranted.

Eleventh, the defense objects to the admission of evidence regarding Fishman's foreign sales as unduly prejudicial, incanting the now-familiar refrain that these products were not misbranded or adulterated because they apparently conformed with the FDCA's "export exemption." Opp'n at 10. Yet Fishman has not, then or now, presented proof that his exports met the legal requirements of that exemption. He is thus not entitled to invoke that affirmative defense. Throughout this litigation, Fishman has failed to point to any evidence establishing that he enjoys the benefit of that exemption. Indeed, in his recent bail revocation submission, Fishman conspicuously argued that he *endeavored* to comply with the export exemption, but never suggested that he actually did so. This is unsurprising insofar as Fishman's own post-arrest communications with his foreign purchaser expressly admit that he failed to satisfy the requirements of the export exemption, and indeed knowingly evaded import licensing restrictions in the United Arab Emirates. *See* Exhibit A at 4. Fishman bears the burden of establishing the "export exemption" as an affirmative defense, and he has not and cannot so demonstrate. The defendant, therefore, should be precluded from raising the export exemption as an affirmative defense unless and until he can demonstrate that there is a legal and factual basis to do so.

Given that there is no evidence supporting such a defense, Fishman should be precluded from offering expert witness testimony—by attorney Ted Sullivan or any other expert witness "with comparable qualifications"—as to the particulars of the export exemption. *See* Opp'n at 11. Setting aside the fact that Fishman never noticed Mr. Sullivan or any other expert witness by the November 18, 2021 reciprocal expert witness disclosure deadline set by the Court,⁵ such expert testimony is in violation of Rule 403. Expert testimony regarding the particulars of an unavailable affirmative defense, unsupported by the facts of this case, is a waste of the jury's time, risks confusing the issues, and is unduly prejudicial.⁶

Twelfth, the defense argues that, notwithstanding Fishman's inadequate expert notice, they should be permitted to offer expert testimony by Dr. Clara Fenger, DVM, in their rebuttal case, and provide the requisite notice under Rule 16 at some later, undefined date. Opp'n at 12-13. The defense has had notice of anticipated expert witness testimony that the Government intends to offer at trial as early as September 30, 2020, *see* Gov't Opp'n Exhibit F, and most recently by the Court-imposed deadline of November 18, 2021, *see* Defs. MIL Exhibit E. It is not the case that two of three of the Government's witnesses "were not even treated as experts in the Government's disclosure." Opp'n at 12. As evidenced by the Government's fulsome prior disclosures of expert testimony by Dr. Cynthia Cole (which the defense's submission ignores), the subject of Cole's expert testimony is plain. The second witness referenced by the defense, Dr. Diana Link, is not

⁵ The defense repeatedly attempts to excuse untimely expert disclosures as necessary for the defense to respond to the Court's ruling on pending motions *in limine*. This is baseless. The parties were well aware—and have been for months—that the defendant's drug exports formed part of this case. Further briefing by both parties in the course of pre-trial litigation has further elucidated the relevance of this conduct.

⁶ Mr. Sullivan's anticipated "expert" testimony, moreover, again invites the same prejudicial "presence of counsel" confusion discussed above insofar as Mr. Sullivan was one of the attorneys with whom Fishman purportedly conferred regarding the legal prerequisites to his business. Introduction of his testimony is further unduly prejudicial insofar as it raises the specter that Fishman complied with Mr. Sullivan's advice.

anticipated to offer any expert opinion; she was present during a search, and will thereby offer testimony of her personal observations as a fact witness. The defense's arguments are merely distracting from the fact that their expert witness notice is substantively deficient and has yet to be supplemented more than a month after the deadline for reciprocal expert witness disclosure passed. As noted in the Government's initial motion, the defense had offered to provide a detailed summary of Dr. Fenger's opinions and anticipated testimony by December 6, 2021; the defense provided no additional records. As it stands today, the defense's expert witness notice is patently insufficient, lacking any particulars as to the drugs Dr. Fenger evaluated, the methodology she employed, or the basis for her conclusions that such drugs are safe and effective. The defense did not supplant its notice with any additional 3500 materials, expert reports, or even the evidence provided to the expert. By contrast, the Government has made detailed disclosures of the anticipated topics of expert testimony for each of its two anticipated expert witnesses, provided 3500 material for these witnesses, and further produced reports prepared by one of its experts. The defense attempts to thread the needle by reserving their right to call Dr. Fenger as a rebuttal witness, claiming that they will make the requisite notice at some undetermined future date after the Court rules on the admissibility of Government's expert witnesses. The Court should rebuff the defense's attempt to excuse their untimely and inadequate expert witness notice. The issues in this trial, and the subjects of expert witness testimony have long been known to the defendants. Defense counsel cannot now "cure" their inadequate notice with a supplemental disclosure at a time of their choosing. Dr. Fenger is not offered by the defense in light of new arguments or theories previously-unknown to defense counsel; the defendants merely seek an extension. There is no good cause for this delay, and the defense fails to offer any compelling reason for it.

Separately, and not in response to the Government's motions, the defense raises new objections to the Government's expert witnesses, including requesting that the Government's experts be precluded from: (1) defining or explaining the elements of the adulteration and misbranding statute, (2) suggesting that the purpose of the statutory scheme is to ensure the well-being and safety of racehorses, or (3) that Fishman's drugs do not meet the FDA standards of "safety and efficacy." Opp'n at 11. The Government has largely addressed these issues in its opposition to the defendants' motions *in limine*, but briefly turns to these issues here.

First, the Government's experts should not be precluded from explaining the FDCA's regulatory regime. Indeed, and by way of example, it would be bizarre for Dr. Jean Bowman, a Food and Drug Administration veterinary medical officer, to be precluded from discussing her roles and responsibilities at the FDA's Center for Veterinary Medicine without outlining key "elements of the adulteration and misbranding statute," Opp'n at 11, such as provisions that prohibit the distribution of unapproved new animal drugs, or the requirement that drug labels contain accurate information. The defense's request is without basis and leads to an illogical result. Courts routinely admit expert testimony regarding overarching standards in regulated industries—whether such duties arise from regulations, industry standards, or otherwise—in cases where such evidence will assist the jury in evaluating the defendant's mental state. Courts in this Circuit routinely admit expert testimony regarding duties under regulatory standards and industry practices.⁷

⁷ See, e.g., *United States v. Nouri*, 711 F.3d 129, 136, 145 (2d Cir. 2013) (evidence was sufficient to uphold commercial bribery conviction based in part on "the government's industry expert" who

Second, and as stated in the Government's opposition, at least one of the Government's expert witnesses is anticipated to testify, based on her personal experience rather than as a matter of expert opinion, that the mission of the FDA is to protect consumers (including animals) and that certain provisions and requirements of the FDCA are imposed for that very reason. There is no basis to preclude this testimony. It is not unduly prejudicial and is, in fact, a reasonable and commonsense implication of the statute's provisions and this witness's experience in this field. The defense cites no authority for their position to the contrary.

Third, it is proper and expected that a qualified expert in the scientific community—*i.e.*, the Government's expert witnesses—would offer testimony that the defendants' drugs are not generally recognized as "safe and effective" for their intended use. Such testimony is appropriately the subject of expert opinion, and has been offered for that very purpose. *See United States v. Writers & Rsch., Inc.*, 113 F.3d 8, 10–11 (2d Cir. 1997) (noting that "[t]he government also offered expert testimony that 714X has not been clinically established as safe and effective for use in the treatment of human diseases nor is the drug generally recognized as safe and effective for that purpose among qualified experts."); *United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension . . .*, 675 F.2d 994, 1000–01 (8th Cir. 1982) (noting Government expert witnesses had offered testimony at trial that drugs "are not generally recognized among qualified experts as safe and effective to treat race track cough or equine urinary tract infections").

testified "about the legal obligations of brokers in dealing with their customers," "FINRA rules," "[i]ndustry rules," and "industry standards"); *United States v. Wiseberg*, 727 F. App'x 1, 4–5 (2d Cir.), *cert. denied sub nom. Kalaba v. United States*, 139 S. Ct. 131 (2018) (evidence was sufficient to uphold conviction for conspiring to illegally distribute prescription narcotics based in part on Government's pharmaceutical expert who testified about the duties and responsibilities of pharmacists under state law); *United States v. Galanis*, 758 F. App'x 71, 74 (2d Cir. 2018) (rejecting argument that district court erred in permitting Government to call a law professor to offer "opinions about the legal standard of materiality, the requirements of Regulation S, and the meaning of certain fiduciary duties"); *see also United States v. Brooks*, No. 06 Cr. 550 (JS), 2010 WL 291769, at *4 (E.D.N.Y. Jan. 11, 2010) (denying defendant's motion *in limine* and authorizing Government's expert to testify about applicable "SEC, OTC, NASDAQ, and AMEX rules," "the fiduciary duties that directors and officers owe a publicly-held corporation," applicable "disclosure and reporting obligations," "SEC regulations concerning related party disclosures," and a corporate executive's "responsibilities" in signing a "representation letter"); *U.S. S.E.C. v. Zwick*, No. 03 Civ. 2742 (JGK), 2007 WL 831812, at *20 (S.D.N.Y. Mar. 16, 2007), *aff'd*, 317 F. App'x 34 (2d Cir. 2008) (jury properly found that defendant acted with requisite mental state based on expert testimony establishing that markups charged by defendant "exceed[ed] industry standards for such markups"); *see also Gill v. Arab Bank, PLC*, 893 F. Supp. 2d 523, 537 (E.D.N.Y. 2012) (denying motion to exclude expert witness who would testify regarding "the customs and practices—specifically, United States banking regulations—under which the Bank operated in the United States" because "[t]he Bank's state of mind is a central issue in this litigation" and "[t]estimony as to the content of banking industry standards and practices—and the Bank's compliance with such standards and practices—will be valuable to a jury likely to be unfamiliar with such topics.").

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